

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

12

EUROPEAN PATENT APPLICATION

21 Application number: 89313341.3

91 Int. Cl.⁵: **A61B 5/14, A61B 5/0215,**
A61M 5/315

22 Date of filing: 20.12.89

30 Priority: 22.12.88 US 288568

43 Date of publication of application:
04.07.90 Bulletin 90/27

84 Designated Contracting States:
AT BE CH DE ES FR GB IT LI NL

71 Applicant: **MEDEX INCORPORATED**
6250 Shier-Rings Road
Dublin Ohio 43017(US)

72 Inventor: **Simpson, Shawn L.**
3706 Woodmont
Toledo, Ohio 43613(US)
Inventor: **Young, Steven E.**
Winding Way
Temperance, Michigan(US)
Inventor: **Musgrove, David G.**
1333 Clubview Boulevard
North Worthington, Ohio 43085(US)

74 Representative: **Allen, Oliver John Richard et al**
Lloyd Wise, Tregear & Co. Norman House
105-109 Strand
London, WC2R 0AE(GB)

54 **Blood sampling apparatus.**

57 Apparatus for withdrawing blood from a tube (10) adapted to be introduced into a patient's blood vessel during blood pressure monitoring includes a branch line (23) connected to the tube (10), the branch line having two branches (29, 30). A storage syringe (35) is connected to one branch (30) of the branch line and a latex self-sealing cap (45) covers the other branch (29) to provide an IV site suitable for penetration with a syringe needle (51) to withdraw a blood sample through the IV site. The storage syringe (35) brings blood to the intersection (48) of the two branches of the branch line so that a sample may be withdrawn through the IV site.

EP 0 376 603 A1

BLOOD SAMPLING APPARATUS

This invention relates to blood pressure monitoring apparatus, and more particularly to apparatus for removing samples of a patient's blood during a blood pressure monitoring procedure.

Blood pressure monitoring apparatus is well known. It includes a catheter inserted into a patient's blood vessel, a tube connecting the catheter to a transducer, a supply of saline solution connected through the transducer to the catheter and a flush valve connected in the line to the catheter. The system through the catheter is filled with the saline solution, the saline solution forming a static column between the patient's blood vessel and the transducer whereby variations in blood pressure are communicated to the transducer so that the patient's blood pressure is monitored in real time. The flush valve has a capillary through which the saline solution flows, very slowly, to the patient. The slow dripping of the saline solution prevents any clotting of blood in the catheter which might introduce an error into the monitoring of the blood pressure. The flush valve contains a bypass by which a rapid flow of saline solution can be introduced into the system as needed.

It has been conventional to provide a site for withdrawing a blood sample. A stopcock is placed in series between the catheter and the transducer. The stopcock has a port that is normally closed by a solid plug (dead ender), the port being covered by a dust cover. The procedure for drawing a blood sample through the free port on the stopcock has required the following major steps: The stopcock is shifted to block flow of saline solution from the supply and open ports between the catheter and the plugged port. The dust cover is removed and the dead ender plug is moved and carefully set aside to avoid contamination. A syringe is inserted in the opening created by the removal of the dead ender and about 2 cc mixture of blood and saline is withdrawn to remove the saline from the catheter and tube leading to the stopcock so that only blood is present at the free port of the stopcock. A heparinized syringe is inserted into the free stopcock port to withdraw about 1 cc of blood. The stopcock is shifted to open the free port to the saline supply and block the port to the catheter. The free port is flushed, using the flush valve, with saline and the dead ender is replaced. The stopcock is then shifted again to block the free port and connect the catheter to the saline supply. The flush valve then flushes the blood out of the tube and catheter, whereupon the system between the catheter and transducer is filled and ready for resumption of normal monitoring operation.

The foregoing procedure has obvious disadvantages.

A number of manipulative steps are required to obtain the blood sample. A number of chances for contamination of the patient's blood are presented in the opening of the port to bring the blood to the stopcock for sampling. Blood usually drips from the sampling port. The exposure of attending people to the patient's blood is a matter of considerable concern because of the possibility of spreading AIDS, hepatitis and the like.

The objective of the present invention has been to provide a simpler system for taking samples of blood from the blood pressure monitoring apparatus wherein the chance for contaminating the patient is substantially entirely eliminated and the possibility of blood inadvertently contaminating the area around the patient is also eliminated.

Apparatus in accordance with the invention for withdrawing blood from a tube adapted for connection to a patient's blood vessel and to a supply of saline solution, a branch line being connected to the tube for removal of a blood sample is characterized in that the branch line has two branches, one branch of which is connected to a storage syringe, the other branch forming an IV site for temporary receipt of a sampling syringe, whereby the storage syringe may temporarily remove blood and saline solution from the tube to bring substantially pure blood to the IV site, whereupon the sampling syringe may withdraw blood from the IV site.

The blood sampling operation, with the apparatus of the present invention, is greatly simplified. The storage syringe withdraws approximately 2 cc of solution from the catheter and tube to bring a pure sample of the patient's blood to the intersection of the two branches of the branch line. A sampling syringe is then introduced through the IV site to withdraw a sample. After the sample has been withdrawn, the storage syringe expels the saline solution back through the circuit to the patient. The flush valve may then be manipulated to clean the system of any residual blood from the sampling process.

From the foregoing, it can be seen that the manipulative steps are greatly reduced by the present invention. The system is not opened to atmosphere so that contaminants cannot be introduced through the free port. The possibility of blood from the patient escaping from the system to contaminate the area around the patient is greatly reduced.

Preferably means are provided between the cylinder of the storage syringe and its plunger so that when the plunger is withdrawn to draw saline into the storage syringe, no contaminants from the

atmosphere can contact the plunger and inadvertently get into the system. The prevention means may consist of a flexible sleeve, preferably bellow-shaped, which is connected between the barrel and the plunger.

The IV site is preferably covered by a self-sealing latex cap. The cap may have a central plug that extends up to the storage syringe branch to provide assurance that when the saline solution is brought into the storage syringe, the blood will be immediately adjacent the latex cap and accessible to the sampling syringe.

Suitably a stopcock is connected between the tube and the saline solution supply, the branch line being connected to a third port of the stopcock. Means may be provided for selectively closing one port, while the other ports remain open. When a sample is to be taken, the stopcock is shifted to block the saline solution supply and so connect the branch line with the tube. Once the sample has been taken, the stopcock may be shifted to block the tube to allow the system to be flushed.

The invention will now be further described by way of example, with reference to the accompanying drawings in which:

Fig. 1 is a diagrammatic elevational view of one embodiment of the blood pressure monitoring apparatus of the invention; and

Fig. 2 is a partial enlarged view, partly in section, of the apparatus of Figure 1.

Referring to Fig. 1 one end of a tube 10 is connected via a catheter to the patient's arm. The other end of tube 10 is connected, by way of a blood sampling stopcock 11, to a blood pressure transducer 12. The blood pressure transducer can be a disposable or reusable transducer such as are well known in the art. The transducer is connected to a monitor 13 by which variations in blood pressure can be viewed and recorded. The blood pressure transducer is connected to a flush valve 15, which is connected to a supply of saline solution 16. The flush valve has a marine capillary tube in series between the saline supply 16 and transducer 12 to assure a continued slow dripping of saline solution through the system to the catheter. A large bypass passageway is provided in the flush valve in parallel with the capillary tube. That large passageway is normally closed and is opened by squeezing the operators 17 to greatly increase the flow of saline solution to the system. Thus far described, the apparatus is conventional and has been in use in hospitals for many years.

The stopcock 11 has three ports 21, 22 and 23. The first port 21 is connected to the tube 10 leading to the catheter. The second port 22 is connected to a tube 25 that leads to the transducer 12. A T-connector 27 has three branches 28, 29, and 30. One of the branches, 28, is connected to

the third stopcock port 23 which forms a branch line from the tube 10.

Internally, the stopcock 11 has a valve rotatable by a handle 34 that can block the flow through any of the three ports 21, 22, 23. Normally, the projecting handle 34 points to the "off" position, that is, the blocked port. In the illustrated position of the stopcock, the port 22 is blocked while flow from the ports 21 and 23 is open.

A storage syringe 35 is mounted on the branch 30 of the T-connector 27. The storage syringe has a barrel 36 and a plunger 37. A bellows-shaped flexible sleeve 40 has one end 41 connected to the barrel 36. The other end of the sleeve 42 is connected to the free end 43 of the plunger 37. It can be seen that the sleeve keeps the plunger free from exposure from contaminants when the plunger is withdrawn to fill the barrel 36.

The branch 29 is closed by a self-sealing latex cap 45. As best shown in Fig. 2, the cap 45 has a skirt 46 surrounding the branch 29 of the T-connector 27. A central plug 47 extends through the branch 29 to the intersection 48 of the T-connector.

A syringe 50 having a needle 51 can penetrate the self-sealing cap 45 to bring the needle into the intersection 48 of T-connector 27 for the purpose of withdrawing a sample.

The T-connector 27 has its branch 28 fixed to the port 23 of the stopcock, for example by means of a solvent. The storage syringe 35 may be connected to the T-connector in any fashion and may include a conventional Luer lock indicated at 52.

During normal operation, the stopcock 11 has its handle 34 overlying the port 23 so as to open the ports 21 and 22 to permit communication between the patient's blood vessel and the transducer and to permit flow of saline solution from the supply 16 to the end of the catheter via the flush valve.

When a blood sample is to be taken, a procedure that may be performed many times during a day, the stopcock handle 34 is turned to the illustrated position blocking port 22. At this time, the tube 10 and stopcock are filled with saline solution. The plunger 37 of the storage syringe 35 is withdrawn to fill the barrel 36 with the saline solution from the tube 10 until blood from the patient runs through the stopcock and into the connector 27. When the blood has presented itself in the connector 27, the syringe 50 is inserted through the self-sealing cap 45 into the intersection 48. There, blood, substantially free of saline solution, is withdrawn. The sampling syringe 50 is then removed. The plunger 37 of the storage syringe is returned to its former position in the barrel 36 to expel the saline solution and blood back through the T-connector 27, stopcock 11, tube 10 into the catheter. The stopcock handle 34 is then returned to the position overlying port 23. The flush valve 15 may

be briefly manipulated to permit fresh saline solution to flow through the bypass passageway to clean any residual blood from the tube 10.

Claims

1. Apparatus for withdrawing blood from a tube adapted for connection to a patient's blood vessel and to a supply of saline solution, a branch line being connected to the tube for removal of a blood sample characterised in that the branch line has two branches (29, 30), one branch (30) of which is connected to a storage syringe (35), the other branch (29) forming an IV site for temporary receipt of a sampling syringe (50), whereby the storage syringe (35) may temporarily remove blood and saline solution from the tube (10) to bring substantially pure blood to the IV site, whereupon the sampling syringe (50) may withdraw blood from the IV site.

2. Apparatus as claimed in claim 1 characterised in that the storage syringe (35) has a barrel (36) and a plunger (37), slidable in and projecting from the barrel (36) and in that means are provided for preventing contamination of the plunger (37) and the interior of the barrel (36).

3. Apparatus as claimed in claim 2 characterised in that the prevention means comprises a flexible sleeve (40) connected between the barrel (36) and the plunger (37) to keep contaminants out of the storage syringe (35).

4. Apparatus as claimed in any preceding claim characterised in that a self-sealing latex cap (45) covers the IV site.

5. Apparatus as claimed in any preceding claim characterised in that the IV site includes a plug (47) which extends to the first branch (30) so that when blood is brought to the intersection (48) of the two branches (29, 30) by means of the storage syringe, the blood will be adjacent the end of the plug (47) ready for sampling.

6. Apparatus as claimed in any preceding claim characterised in that a stopcock (11) is connected between the tube (10) and the saline solution supply (16), the branch line being connected to a third port (23) of the stopcock, means (34) being provided for selectively closing one port, while the other ports remain open.

5

10

15

20

25

30

35

40

45

50

55

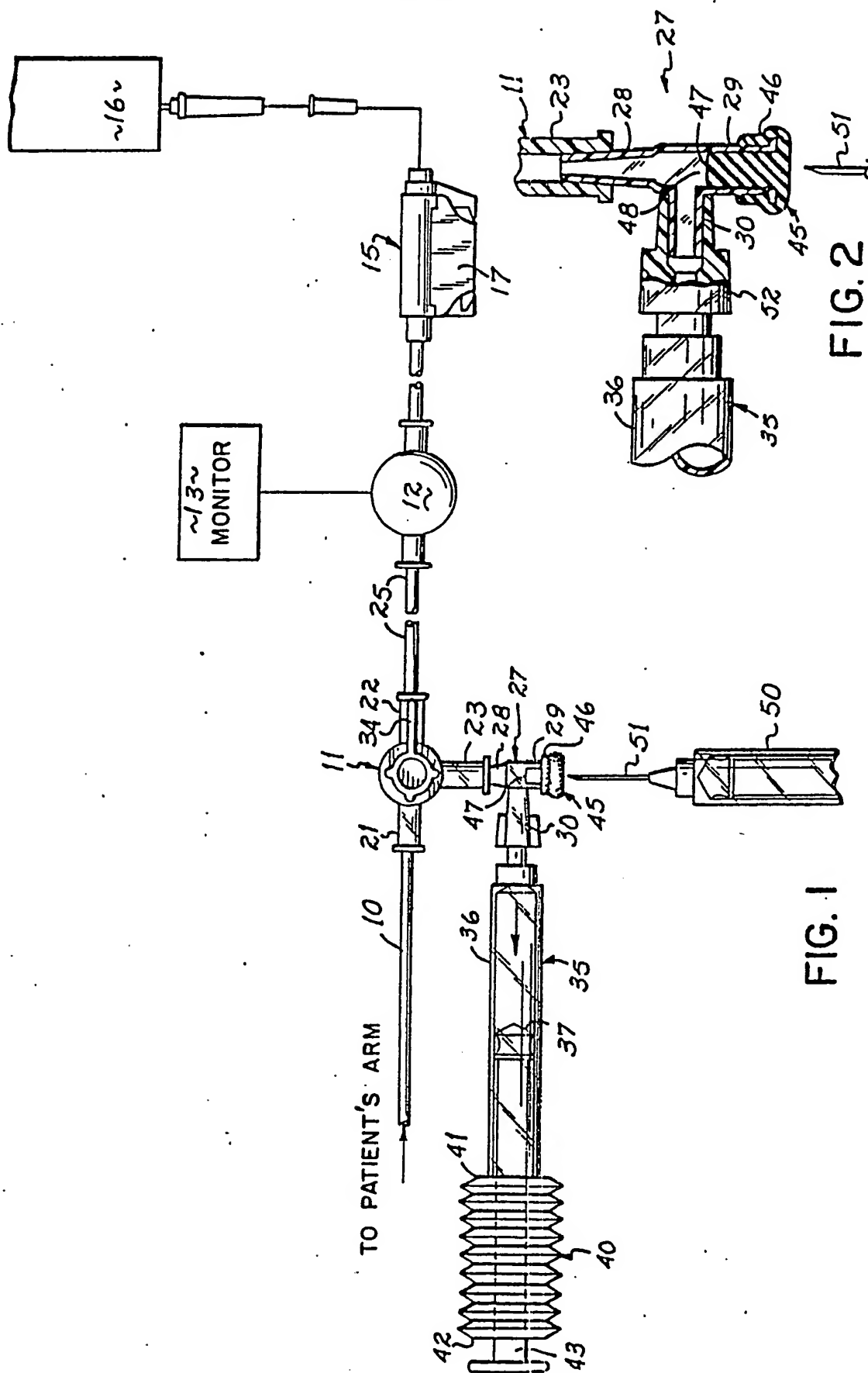


Fig. 1

FIG. 2